APR 2 8 2004

K040709

510(k) Summary

Safety and Effectiveness Summary
In Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act

1. General Provisions

Device Trade Name: Protos Software
Common Name: Dosimetry Analysis Software

Applicant Name and Address:

AKTINA Medical Physics Corporation
360 North Route 9 W
Congers, New York, 10920
Phone: 914-268-0101
FAX: 914-268-1700
Registration Number: 2436865

2. Name of Predicate Device

Radiological Imaging Technology, Inc., RIT 113 Film Analysis System, K935928

Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seg. (1977).

3. Classification

This device is classified as a class II device according to 21 CFR 892.5050

4. Performance Standards

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this product.

5. Intended Use and Device Description

The intended purpose of the Protos Software is to provide a Radiation Therapy Quality Control (QC) tool that allows for the automated and rapid comparison of predicted and measured radiation dose values. The software is intended for the QC of external beam radiation treatments. Measured data will be acquired from radiographic films. Predicted data will be calculated in a Radiotherapy Treatment Planning System (RTPS) and transferred to the software via a Digital Imaging and Communications in Medicine (DICOM) protocol.

6. Technological Characteristics

The Aktina Medical Physics' Protos Software has the same technological characteristics as the RIT 113 Film Analysis System (Radiological Imaging Technology, Inc., K935928). Both systems:

a. Consist of Dosimetric Analysis software
b. Import predicted radiation dosimetry data from treatment planning systems
c. 0Import measured radiation dosimetry data imported from a film scanner; radiographic films are obtained from an IMRT phantom.
d. Are used as Radiation Therapy Quality Control (QC) tools that allow for the automated and rapid comparison of predicted and measured radiation dose values
e. Require personnel trained in the use of Radiation Therapy equipment.
f. Require a Microsoft Windows or equivalent computer environment.

7. Biocompatibility

The Aktina Medical Corporation Protos Software does not come into contact with the patient and therefore does not require biocompatibility testing.

8. Summary of Substantial Equivalence

This device is similar in design and intended use and performance characteristics to the predicate device. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2004

Mr. Tony Spaccarotella
Director, QA/RA
Aktina Medical Corporation
360 North Route 9W
CONGERS NY 10920

Re: K040709
Trade/Device Name: Protos Software
(Model 11-860)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle
Radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: March 15, 2004
Received: March 18, 2004

Dear Mr. Spaccarotella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K040709

Device Name: Protos Software

Indications for Use:

External Beam Radiation Therapy is typically delivered to patients from a linear accelerator with either photon or electron beams, or from a radioactive source (high and low dose rate variants). AKTINA Medical Physics Corporation has designed and manufactured software to aid in the verification of the delivery process prior to radiotherapy treatment. The software analyzes and compares the predicted data from a treatment planning computer to measured data from delivered dose measurements.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ or Over-The Counter Use: (Per 21 CFR 801.109)

David R. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040709